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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,427	09/16/2003	Daniel R. Marshall	10002305-4 H303.190.103	1562

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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,427	MARSHALL, DANIEL R.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 25-37 have been amended. Claims 23-42 are pending.
2. The objections to Specification are WITHDRAWN in view of the Amendment.

Response to Arguments

3. Applicant's arguments with respect to claims 23-42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al, US 6,285,897 B1 ("Kilcoyne"), in view of Gibson et al, US 5,557,596 A ("Gibson").

Claims 38 and 40: Kilcoyne teaches a method of recording data (physiological data) internally within a human body (within a body lumen of a person) (see col. 3, lines 2-10) comprising: placing (implanting) a capsule 18 (monitor) within a digestive track (esophagus or other body lumens or cavities) of a human body, the capsule 18 including a sensor 110 (transducer) and a storage device 116 (memory chip or microprocessor including temporary storage or memory of data) (see col. 4, lines 61-63,

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and col. 6, lines 20-26); sensing a biological condition (gastroesophageal reflux, GERD, or intrasophageal) within the human body with the sensor 110. In addition, Kilcoyne teaches a microprocessor 116 and computer software program for performing one or more logical operations (functions) using the sensed biological condition (physiological data), selectively (temporarily) recording the sensed biological condition to the storage device 116 based upon the logical operations, and accessing programmable logic from the storage device (microprocessor performing one or more functions) (see col. 3, lines 28-31, and col. 6, lines 18-44).

Kilcoyne teaches a memory chip but does not specifically teach an atomic resolution storage device. However, Gibson teaches an atomic resolution storage device 100 (see fig. 1). It would have been obvious for one of ordinary skill in the art to modify Kilcoyne with Gibson's atomic resolution storage device in order to increase the storage density and reduce the cost/storage in information storage devices, such as Kilcoyne's memory chip (see Gibson, col. 1, lines 14-21).

Claims 41 and 42: Kilcoyne teaches a memory chip 116 and does not teach the subject matter as claimed in regards to a specific memory storage device. However, Gibson teaches a method of recording data using an ultra-high density storage device comprising: generating an electron beam current (using field emitter 102), bombarding a storage area 108 of the atomic resolution storage device 106 (storage medium) with the electron beam current to record data representative of the sensed biological condition, and positioning the storage area to be bombarded by the electron beam current (using micromover 110) (see fig. 1, col. 2, lines 10-30, and col. 3, lines 30-35). It would have

been obvious for one of ordinary skill in the art at the time the invention was made to modify Kilcoyne's memory chip 116 with an ultra-high density storage device as taught by Gibson in order to provide increase storage density and provide fast times and high data rates (see Gibson, col. 1, lines 45-62).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 23-27, 29-34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne in view of Gibson and further in view of Iddan et al, US 5,604,531 A ("Iddan").

Claim 23: Kilcoyne teaches a method of recording data (physiological data) internally within a human body (within a body lumen of a person) (see col. 3, lines 2-10) comprising: sensing a predetermined type of biological condition (gastroesophageal reflux, GERD, or intrasophageal) within the digestive tract (esophagus or other body lumens or cavities) with a sensor 110 (transducer) disposed within a capsule 18 (monitor) (see col. 4, lines 9-14, and col. 5, lines 14-30); and recording the sensed biological condition as data in memory module 116 (memory chip or microprocessor including temporary storage or memory of data) within the capsule 18 while the capsule 18 is in the digestive tract (see col. 4, lines 61-63, and col. 6, lines 20-26).

Kilcoyne teaches a memory chip but does not specifically teach an atomic resolution storage device. However, Gibson teaches an atomic resolution storage

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device 100 (see fig. 1). It would have been obvious for one of ordinary skill in the art to modify Kilcoyne with Gibson's atomic resolution storage device in order to increase the storage density and reduce the cost/storage in information storage devices, such as Kilcoyne's memory chip (see Gibson, col. 1, lines 14-21).

Kilcoyne teaches implanting an inert capsule (monitor 18) within the digestive tract. Kilcoyne does not explicitly teach "ingesting", or "swallowing", the inert capsule. However, Iddan teaches ingesting an inert capsule (swallowable capsule) within a digestive tract (digestive system) of a human body and sensing physiological parameters (see col. 3, lines 3-17 and 38-40). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kilcoyne's method to include the step of "ingesting" or "swallowing" the monitor 18 in order to have the monitor move easily through the digestive system (see Iddan, col. 1, lines 35-40).

Claims 24 and 25: Kilcoyne teaches retrieving the sensed data from memory module 116 when the capsule 18 is outside of the human body, and capturing the capsule 18 after passage of the capsule 18 through the digestive tract (see col. 4, line 63 to col. 5, line 1).

Claim 26: Kilcoyne teaches transmitting the data from the capsule 18 to a location outside of the human body while the capsule 18 is within the human body (see col. 4, lines 50-54).

Claim 27: Kilcoyne does not teach the subject matter as claimed. However, Iddan teaches obtaining an image (image or video data) of a predetermined body location (see col. 3, lines 12-22). It would have been obvious for one of ordinary skill in the art at

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the time the invention was made to modify Kilcoyne's method to include a step of obtaining an image or video of a predetermined body location within the digestive tract in order to provide autonomous video endoscopy while sensing physiological parameters (see Iddan, col. 1, lines 50-54).

Claims 29-33: Kilcoyne teaches exposing a chemical sensor array 110 (pH sensor) on the surface of the capsule to sense one or more chemical conditions (pH level) in the digestive tract, sensing at least one of a relative amount (pH) and an absolute amount of at least one or more digestive tract constituents (measuring one or more of the other physiological parameters such as ion levels and solute concentrations), sensing a pH of the digestive tract constituents, exposing an electrically based sensor in the capsule to sense biologic conditions, sensing a temperature within the digestive tract (see col. 5, lines 15-57).

Claim 34: Kilcoyne teaches performing the sensing step at a predetermined body location (positioning and sensing within the esophagus) within the digestive tract that corresponds to a known location for the predetermined biologic condition (see col. 4, lines 18-21).

Claim 36: Kilcoyne teaches recording sensed data continuously (in real time) within the digestive tract (see col. 4, lines 50-52).

Claim 37: Kilcoyne teaches initiating and maintaining recording of the sensed data when the sensed data reaches a predetermined value of a predetermined biologic condition (initiating and recording the physiological parameter data at predetermined

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intervals needed to establish the diagnosis of GERD) (see col. 4, lines 50-58, and col. 5, lines 5-13).

6. Claims 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne in view of Gibson and Iddan, as applied to claims 24 and 34 above, and further in view of DeMarco, US 5,353,807 A ("DeMarco").

Claims 28 and 35: Kilcoyne in view of Iddan does not teach the subject matter as claimed. However, DeMarco teaches method for using a magnetically guidable intubation device, comprising: arranging a magnetic member in the capsule 56 (self contained magnetically guidable member) prior to the ingesting (swallowing) (see col. 12, line 65 to col. 13, line 5, and col. 13, lines 20-34); arranging a magnet positioner 32 (external magnetic field applying means) outside the body (see col. 14, lines 16-20); magnetically manipulating the relative position and orientation of the capsule 56 within the digestive tract (intestine) by using the magnet positioner 32 to move the magnetic member in the capsule 56 (see col. 14, lines 9-41); and identifying the passage (position or location) of the capsule 56 at a predetermined location within the digestive tract using at least one of a radiographic technique (x-ray) and an ultrasonic technique (ultrasound device) (see col. 14, lines 27-30). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kilcoyne to magnetically guide monitor 18 and identify its location using x-ray or ultrasound techniques in order to provide a device which can be effectively magnetically guided within the interior of a

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body to perform a diagnostic and therapeutic medical procedure which is easy to use and can be accurately positioned (see col. 2, lines 19-32).

7. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne in view of Gibson, as applied to claim 38 above, and further in view of Iddan.

Claim 39: Kilcoyne does not teach the subject matter as claimed. However, Iddan teaches receiving video (video data) via a video receiver 24 (camera system) (see col. 3, lines 12-22 and 27-37). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kilcoyne's method to include a step of receiving video of the esophagus in order to provide autonomous video endoscopy while sensing physiological parameters (see Iddan, col. 1, lines 50-54).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Navin Natnithithadha', is positioned above the printed name.

Navin Natnithithadha
Patent Examiner
GAU 3736
23 January 2006